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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,144	07/13/2005	Juan Ramella	P70596US0	9818

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

WIEST, PHILIP R

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,144

Applicant(s)

RAMELLA, JUAN

Examiner

Phil Wiest

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10 and 18 is/are rejected.
- 7) ☒ Claim(s) 5-9, 11, 16, 17, 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

In the amendment filed 4/23/07, applicant amended Claims 1-11 and added Claims 16-20. Claims 12-15 remain withdrawn. Claims 1-20 are currently pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat (US 5,269,924) in view of Macabasco et al. (US 5,573,527).
3. With respect to Claims 1 and 2 Rochat discloses a blood collecting and filtering apparatus 10 comprising two outer sheets and a flexible inner sheet 12 that divides the interior of the bag into a first chamber 13 and second 14 chamber (see Figure 1). The

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inner sheet comprises a screen that extends to the distal end (bottom end) of the bag). The two outer sheets and inner sheet are water-tightly joined at a periphery of the bag. A circular access bushing (21, 15, 16) is placed in fluid communication with the chambers such that it provides an inlet line into the first chamber and a discharge line in communication with the second chamber (see Figure 1). Rochat further discloses that the entire outer wall of the bag is watertight (Column 2, Lines 47-63). Rochat, however, does not disclose that the bushing is affixed on the side wall of the bag via a first and second aperture in the inner sheet and one of the outer sheets. Macabasco et al. disclose a medical bag comprising a bushing 114 built directly into the side of the bag 102. It would have been obvious to one skilled in the art at the time of invention to modify the blood collecting and filtering apparatus with the bushing location of Macabasco et al. in order to remove filtered fluid from a different location on the bag. Regarding Claim 2, Macabasco and Rochat both disclose bushings which are annular on the plane which projects toward the bag. The repositioning of the bushing to the side of the bag, such that an aperture would be created in the sheets provides the same functionality as the device of Rochat, and the repositioning of the bushing to the side would have an obvious rearrangement to one of ordinary skill in the art in view of the prior art. See MPEP § 2144.04.

4. Claims 3, 4, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat in view of Macacasco et al., further in view of Mathieu (US 5,616,305).

5. With respect to Claims 3 and 4, Rochat and Macabasco et al. disclose the blood bag of Claim 1 (see above rejection). Rochat and Macabasco et al., however, do not disclose that the first chamber is at least partially filled with a powdered solute. Mathieu discloses a hemodialysis packaging unit comprising a layer of sodium bicarbonate powder 74 (Column 9, Lines 47-55). The use of sodium bicarbonate for dialysis treatment of blood is established in the art, especially when used in conjunction with blood bags. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the blood bag system of Rochat and Macabasco et al. with the layer of sodium bicarbonate of Mathieu in order to allow for dialysis treatment of the blood. Furthermore, in the blood bag system disclosed by Rochat, it is inherent that the layer of sodium bicarbonate would be located in the first chamber 13, before the filtering layer 18, in order to prevent particles from mixing into the blood.

6. With respect to Claim 10, Rochat discloses that the inner, screen-like sheet comprised a mesh filter 12 with openings between 100 and 1000 microns that is capable of retaining an undissolved powder solute (Column 2, Lines 40-47).

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rochat in view of Macabasco et al., and further in view of Verkaart et al. (US 2002/0030002). Rochat discloses a bicompartiment bag comprising a first and second flexible outer sheet, a flexible inner sheet 12 dividing the bag into a first and second chamber and having a perforated filter portion at the bottom of the bag. The inner and outer sheets are water-tightly sealed at the peripheries such that no leaks occur. Rochat further

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discloses a bushing (21, 15, 16) having a first and second flow channel therein to provide fluid communication between the first and second chambers. The bushing (21, 15, 16) comprises a plurality of cover members (17, 22) that create an air-tight seal around the bag. Rochat, however, does not disclose that the bushing is disposed on a side wall of the bag via a first and second aperture in the inner sheet and one of the outer sheets, nor does Rochat disclose a cover for sealing the entrance to the flow channels.

Macabasco et al. disclose a medical bag comprising a bushing 114 built directly into the side of the bag 102. It would have been obvious to one skilled in the art at the time of invention to modify the blood collecting and filtering apparatus with the bushing location of Macabasco et al. in order to remove filtered fluid from a different location on the bag. The repositioning of the bushing to the side of the bag, such that an aperture would be created in the sheets provides the same functionality as the device of Rochat, and the repositioning of the bushing to the side would have an obvious rearrangement to one of ordinary skill in the art in view of the prior art. See MPEP 2144.04.

Vekaart et al. discloses a filter bag system comprising a fluid inlet and a fluid outlet. The fluid outlet comprises a removable cover portion 226 that acts as a sealing valve, said valve being openable to provide fluid communication through the channel [0022]. The removable cover 226 prevents the contamination of the fluid line by external air prior attaching a conduit, thereby reducing the risk of infection of the blood. The step of providing a sealing means to the ends of a conduit to prevent contamination is well established in the art of medical fluid containers. Therefore, it would have been

obvious to one of ordinary skill in the art at the time of invention to combine the device of Rochat in view of Macabasco et al. with the tube sealing means of Vekaart et al. in order to prevent fluids from entering the tube before it is connected to a blood source, thereby preventing infection.

Allowable Subject Matter

8. Claims 5-9, 11, 16, 17, 19, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art teaches blood bag of Claim 1, but does not teach the layer attached to the second chamber and made from a woven or injected material, a bushing having a radial tube extending through a discoid base, the communication between sections of the bushing, the thin sheet with strength lines in a cross-shaped configuration, or the thread means for attaching the bag to the bushing. Additionally, the prior art does not teach or suggest a cover having a radial projection toward a contour of the cover and terminating in a peripheral groove at the contour so as to communicate with said second flow channel of the bushing.

Response to Arguments

9. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Claims 1, 2, and 10, applicant argues that there is no motivation to combine the references of Rochat and Macabasco. Rochat teaches the invention substantially as claimed with the exception of the bushing location on the side of the bag. The Macabasco reference serves to show that the placement of a bushing on the side of a bag is established in the art. Placement of a dual-lumen bushing in the same location would have been an obvious relocation that would require very few structural changes and no functional changes to the bag of Rochat, as discussed above.

With respect to Claims 3 and 4, applicant argues that the Rochat, Macabasco, and Matthieu references do not fully anticipate the claim and that there is no motivation to combine. Rochat in view of Macabasco discloses the device as claimed, as discussed above. Furthermore, Matthieu teaches a blood bag system comprising the use of sodium bicarbonate for hemodialysis treatment. Because the use of sodium bicarbonate in a blood bag treatment system is established in the art, it would have been obvious to one of ordinary skill in the art to place sodium bicarbonate in the device of Rochat in view of Macabasco so that the device could be used for hemodialysis treatment.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
7/11/07



LOAN H. THANH
PRIMARY EXAMINER